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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,557	01/03/2002	Terry M. Fredeking	7841P001	8399

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EXAMINER
CHONG, YONG SOO

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
06/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/038,557	FREDEKING ET AL.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

In view of the Appeal Brief filed on 1/31/2007, PROSECUTION IS HEREBY REOPENED.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

Claim(s) 1-12 have been cancelled. Claim(s) 13-26 are pending and examined herein. The obviousness rejection of the last Office Action has been withdrawn from record. The following new rejections will now apply.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-16, 18-22, 24-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for process of increasing the level of interleukin-1 receptors and tumor necrosis factor receptors, does not reasonably provide enablement for all cytokine receptors in the blood. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the breadth of the claims; (4) the amount of direction or guidance presented; (5) the predictability or unpredictability of the art; (6) the relative skill of those in the art; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The Nature of the Invention: The rejected claims are drawn to an invention which pertains to a process of contacting the blood or a fraction thereof with a tetracycline or a

tetracycline-like compound thereby increasing the level of any and every cytokine receptor in the blood and then isolating the blood fraction with the increased cytokine receptor.

(2) State of the Prior Art: The state of the art regarding tetracyclines and cytokines receptors is relatively high, however the relationship of increasing any and every cytokine receptor in the blood with a tetracycline is low.

(3) Breadth of Claims: The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass any and every cytokine receptor in the blood.

(4) Guidance of the Specification: The guidance of the specification as to the cytokine receptors that are increased by tetracyclines is limited to interleukin-1 and tumor necrosis factor receptors.

(5) The Predictability or Unpredictability of the Art: The invention is directed to any and every cytokine receptor in the blood.

(6) The Relative Skill of those in the Art: One of ordinary skill in the art does not know how to increase any and every cytokine receptor in the blood with a tetracycline.

(7) Working Examples: The specification is again limited to only interleukin-1 and tumor necrosis factor receptors.

(8) The Quantity of Experimentation Necessary: The specification fails to provide support for the process of increasing any and every cytokine receptor in the blood with a tetracycline. Nor does it provide information to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that "a patent is not a

hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim(s) 13-14, 16-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobson et al. (*N. Engl. J. Med.* 1997 May 22, 336 (21): 1487-93).

Jacobson et al. discloses treatment of oral ulcers in HIV patients by administrating thalidomide (abstract). Laboratory assays from the blood of the patients were taken to measure for cytokines and cytokine receptors. Measurements of plasma samples resulted in increased levels of tumor necrosis factor and tumor necrosis factor receptors (pg. 1488, right column, second paragraph). Examiner notes that taking laboratory assays from the blood of the patients inherently meets the limitation regarding isolating the blood or the fraction thereof. Furthermore, Jacobson et al. discloses measuring the plasma samples, which inherently meet the limitation regarding further processing of the isolated blood by means such as centrifugation. Upon centrifugation, blood is inherently separated into fractions containing globulin, anti-hemophilia factor, albumin, serum, and plasma.

Examiner also notes that the limitation regarding a three-fold increase of cytokine receptors as a result of administration of a tetracycline is inherent since a composition and its properties are inseparable. "Products of identical chemical composition can not have mutual exclusive properties." Any properties exhibited by or benefits from are not given any patentable weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the disclosed properties are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product.

Furthermore, the list of diseases are considered preamble and also will not be given any patentable weight. It is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish from each other. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Thus, the intended use of a composition claim will be given no patentable weight.

It is further respectfully pointed out that a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for

completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). See MPEP 2111.02.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 15 is rejected under 35 U.S.C. 103(a) as being obvious over Jacobson et al. (*N. Engl. J. Med.* 1997 May 22, 336 (21): 1487-93) as applied to claims 13-14, 16-26 in view of Golub et al. (US Patent 6,015,804).

The instant claims are directed to a process comprising contacting blood or a fraction thereof with a tetracycline or tetracycline-like compound *in vitro* and then isolating the blood or fraction thereof.

Jacobson et al. teach as discussed above, however fail to disclose contacting the blood with a tetracycline or tetracycline-like compound *in vitro*.

Golub et al. teach contacting tetracycline with blood *in vitro* in order to measure increases in levels of cytokines, such as IL-10 (col. 5, lines 54-55; col. 8, lines 8-12; and examples), which then can be administered to treat diseases or conditions, such as inflammation, diabetes, cancer, graft versus host disease, inflammatory bowel disease, arthritis, autoimmune disorders, and rheumatoid arthritis (col. 2, lines 6-18).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, for Jacobson et al. to have also performed the *in vitro* procedure of contacting the blood or a fraction thereof with a tetracycline or tetracycline-like compound as disclosed by Golub et al.

A person of ordinary skill in the art would have been motivated to perform the *in vitro* procedure of contacting the blood or a fraction thereof with a tetracycline or tetracycline-like compound because: (1) both Jacobson and Golub et al. utilize tetracycline or tetracycline-like compounds for therapeutic means; (2) both Jacobson and Golub et al. disclose increasing the level of cytokines in the blood; and (3) in order to corroborate the *in vivo* results disclosed by Jacobson et al. of contacting the blood with a tetracycline or tetracycline-like compound.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER